IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: S. SCHRAGA Confirmation No. 8544

Serial No: 10/641,142 Group Art Unit: 3731

Filed: August 15, 2003 Examiner: T. V. Nguyen

For : ADJUSTABLE LANCET DEVICE AND METHOD

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Window, Mail Stop <u>Appeal Brief-Patents</u>
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This appeal is from the Examiner's final rejection of claims 1-3, 8-14, 17-33 and 35-48 as set forth in the Final Office Action of August 12, 2009. A Notice of Appeal, in response to the Final Office Action, was filed with the required extension of time on January 12, 2010.

A check in the amount of \$270.00 is being concurrently submitted as payment of the requisite fee under 37 C.F.R. 41.20(b)(2). No additional fee is believed to be required for filing the instant Appeal Brief. However, if for any reason a necessary fee is required for consideration of the instant paper, authorization is hereby given to charge the fee for the Appeal Brief and any necessary extension of time fees to Deposit Account No. 19-0089.

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(I) REAL PARTY IN INTEREST

The real party in interest is Stat Medical Devices, Inc. by an assignment recorded in the U.S. Patent and Trademark Office on August 15, 2003, at Reel 014396 and Frame 0767.

(II) RELATED APPEALS AND INTERFERENCES

No related appeals and/or interferences are pending. Appellant notes that this application was subject to a previous Appeal to the Board of Patent Appeals and Interferences. The Board affirmed the Examiner in Appeal No. 2007-1749 decided March 28, 2008. The claims which are the subject to the instant Appeal have been amended following the Board decision.

(III) STATUS OF THE CLAIMS

Claims 1-3, 8-14, 17-33 and 35-48 stand finally rejected. Claims 1-14, 17-33 and 35-48 are pending. Claims 4-7 stand withdrawn. Claims 15, 16 and 34 are canceled. Claims 1-3, 8-14, 17-33 and 35-48 are the subject of this appeal. The claims in issue are attached in the "Claims Appendix".

(IV) STATUS OF THE AMENDMENTS

A Response under 37 C.F.R.§ 1.116 was filed October 13, 2009, requesting reconsideration of the finally rejected claims. The Examiner responded with an Advisory Action mailed on November 13, 2009, indicating that the Response was considered, but did not place the application in condition for allowance. Appellant submits that no other amendments after final have been filed; however, all amendments to the claims have been entered.

(V) SUMMARY OF THE CLAIMED SUBJECT MATTER

A. The Claimed Subject Matter

1. INDEPENDENT CLAIM 1

With reference to page 13, line 4 to page 53, line 26 (i.e., paragraphs [0023] – [0074]) of the instant application and to e.g. Figs.29-40, and by way of non-limiting example, the invention provides for a lancet device LD, comprising a body 501m/501n/402, a trigger 409 movably mounted to the body, and a front cover 403 removably mounted to the body and comprising a skin engaging end P that includes a lancet opening LO through which a lancet needle may extend. A holding member 404/405 and/or 504/505 is movably mounted within the body and comprises a front end and a rear end. A main spring 406 is disposed inside the body between the front and rear ends of the holding member 404/405 and/or 504/505 (see Fig. 36). The front end 404/504 is configured to receive a lancet 10. A first stop surface MSS moves with the holding member 404/405 and/or 504/505 and that is arranged closer to the front end of the holding member 404/405 and/or 504/505 than to the rear end of the holding member 404/405 and/or 504/505 (see Fig. 36). A second stop surface FSS is non-movably coupled to the body. The second stop surface FSS extends inwardly (on portion 402b) from the body, is arranged closer to a front end of the body than to a rear end of the body, and is arranged between the first stop surface MSS and the skin engaging end P. At least partial rotation of the front cover 403 causes the skin engaging end P to move axially relative to the second stop surface FSS. Contact between the first MSS and second FSS stop surfaces defines a puncturing position of the lancet needle (see e.g., Fig. 4). See also paragraphs [0053] – [0065] of the instant application.

2. INDEPENDENT CLAIM 43

With reference to page 13, line 4 to page 53, line 26 (i.e., paragraphs [0023] – [0074]) of the instant application and to e.g. Figs. 29-40, and by way of non-limiting example, the invention provides for a lancet device LD, comprising a body 501m/501n/402, a front cover 403 comprising a skin engaging end P that includes a lancet opening LO through which a lancet needle may extend, and a holding member 404/405 and/or 504/505 movably mounted within the body. The holding member 404/405 and/or 504/505 comprises a front end and a rear end. The front end 404/504 is configured to receive a lancet 10. A main spring 406 is disposed inside the body and between the front and rear ends of the holding member 505. A first stop surface MSS is arranged on a front portion of the holding member 404/405 and/or 504/505 and being disposed inside the body. A second stop surface FSS is axially retained to a front portion of the body and is disposed inside the body. At least partial rotation of the front cover 403 causes the skin engaging end P to move axially relative to the second stop surface FSS. Contact between the first MSS and second FSS stop surfaces defines a puncturing position of the lancet needle (see e.g., Fig. 4). See also paragraphs [0053] – [0065] of the instant application.

3. INDEPENDENT CLAIM 44

With reference to page 13, line 4 to page 53, line 26 (i.e., paragraphs [0023] – [0074]) of the instant application and to e.g. Figs. 29-40, and by way of non-limiting example, the invention provides for a lancet device LD, comprising a body 501m/501n/402, a trigger 409, and a front cover 403 comprising a skin engaging end P that includes a lancet opening LO through which a lancet needle may extend. A holding member 404/405 and/or 504/505 is movably mounted within the body.

The holding member 404/405 and/or 504/505 comprising a front end and a rear end. The front end is configured to receive a lancet 10. A first spring 406 disposed inside the body between the front end of the holding member 404/405 and/or 504/505 and a surface FSS of the body. A back cap 412 is configured to move the holding member 404/405 and/or 504/505 to a retracted position (see Fig. 32). The back cap 402 has a portion which extends within a rear portion of the body (see Fig. 32). A second spring 415 disposed between the rear end of the holding member 404/405 and/or 504/505 and a surface 412c of the back cap 412. A first stop surface MSS is coupled to a front portion of the holding member 404/405 and/or 504/505 and is disposed inside the body. A second stop surface FSS is axially retained to a front portion of the body and is disposed inside the body. At least partial rotation of the front cover 403 causes the skin engaging end P to move axially relative to the second stop surface FSS. Contact between the first MSS and second FSS stop surfaces defines a puncturing position of the lancet needle (see e.g., Fig. 4). See also paragraphs [0053] – [0065] of the instant application.

4. INDEPENDENT CLAIM 45

With reference to page 13, line 4 to page 53, line 26 (i.e., paragraphs [0023] – [0074]) of the instant application and to e.g. Figs. 29-40, and by way of non-limiting example, the invention provides for a lancet device LD, comprising a body 501m/501n/402, a trigger 409 mounted to the body, and a removable front cover 403 comprising a skin engaging end P that includes a lancet opening LO through which a lancet needle may extend. A holding member 404/405 and/or 504/505 is movably mounted within the body. The holding member 404/405 and/or 504/505 comprising a rear end and a front end configured to receive a lancet 10. A wall 501n arranged within the

[housing] body and comprising an opening 501d which allows a portion of the holding member 404/405 and/or 504/505 to pass therethrough. A first spring 406 structured and arranged to move the holding member 404/405 and/or 504/505 to an extended position and comprising one end which contacts a portion of the holding member 404/405 and/or 504/505. A second spring 415 structured and arranged to move the holding member from the extended position to an intermediate position. A first stop surface MSS arranged on the holding member 404/405 and/or 504/505 and being disposed inside the body at a location that is closer to a front end of the body than to a rear end of the body when the holding member 404/405 and/or 504/505 is in the intermediate position. When the holding member 404/405 and/or 504/505 is positioned in a trigger-set position (see, e.g., Figs. 33, 36 and 37). The front end of the holding member 404/405 and/or 504/505 is arranged on a front side of the wall 501n and the rear end of the holding member 404/405 and/or 504/505 is arranged on back side of the wall 501n. Contact between the first MSS and second FSS stop surfaces defines the extended position (see e.g., Fig. 4). See also paragraphs [0053] – [0065] of the instant application.

(VI) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 41 and 42 are improperly rejected as anticipated under 35 U.S.C. §102(b) or, in the alternative, as obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 4,469,110 to SLAMA alone.

Whether claims 1-3, 8-14, 17-33 and 35-48 are improperly rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,469,110 to SLAMA in view of U.S. Patent No. 6,156,051 to SCHRAGA.

(VII-A) ARGUMENT RE. 102(b)/103(a) REJECTION

REJECTION OF DEPENDENT CLAIM 41 UNDER 35 U.S.C. § 102/103 IS IN ERROR

The rejection of claim 41 under 35 U.S.C. § 102(b) as anticipated or as unpatentable under 35 U.S.C. § 103(a) over US patent 4,469,110 to SLAMA is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

The Examiner asserts that he may properly ignore the lancet device features recited in claim 41, i.e., those of claim 1 from which claim 41 depends, and finds that this claim is therefore disclosed or suggested by SLAMA.

Appellant disagrees. Appellant acknowledges that claim 41 is a method claim which depends from lancet device claim 1. Appellant, however, does not agree that the lancet device features of claim 1 can be ignored.

Nor can it reasonably be argued that claim 41 can properly be considered without the features of claim 1. Method claim 41 recites features such as "the needle", "the front cover", "the skinengaging end", "the lancet device", and "the trigger". Each of these claim features finds antecedent basis in claim 1 from which claim 41. Thus, it is clear that claim 41 must be interpreted as reciting the features in claim 1.

Appellant submits that the above-noted document fails to disclose or suggest the features recited in at least independent claim 1 in combination with claim 41. Because no proper modification of the above-noted document discloses or suggests at least the above-noted features of the instant invention, Appellant submits that no proper modification of this document can render unpatentable the combination of features recited in at least these claims.

Appellant requests that the Examiner reconsider and withdraw the rejection of the abovenoted claims under 35 U.S.C. § 102(b)/103(a).

REJECTION OF DEPENDENT CLAIM 42 UNDER 35 U.S.C. § 102/103 IS IN ERROR

The rejection of claim 42 under 35 U.S.C. § 102(b) as anticipated or as unpatentable under 35 U.S.C. § 103(a) over US patent 4,469,110 to SLAMA is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

The Examiner asserts that he may properly ignore the lancet device features recited in claim 42, i.e., those of claim 1 from claim 42 depends, and finds that this claim is therefore disclosed or suggested by SLAMA.

Appellant disagrees. Appellant acknowledges that claim 42 is a method claim which depends from lancet device claim 1. Appellant, however, does not agree that the lancet device features of claim 1 can be ignored.

Nor can it reasonably be argued that claim 42 can properly be considered without the features of claim 1. Method claim 42 recites features such as "the needle", "the front cover", "the skinengaging end", the lancet device", and the trigger". Each of these claim features finds antecedent basis in claim 1 from which claim 42. Thus, it is clear that claim 42 must be interpreted as reciting the features in claim 1.

As such, claim 42 cannot be interpreted without any reference to claim 1 as noted by the Examiner.

Appellant submits that the above-noted document fails to disclose or suggest the features recited in at least independent claim 1 in combination with claim 42. Because no proper

modification of the above-noted document discloses or suggests at least the above-noted features of the instant invention, Appellant submits that no proper modification of this document can render unpatentable the combination of features recited in at least these claims.

Appellant requests withdraw and/or reversal of the rejection of the above-noted claim under 35 U.S.C. § 102(b)/103(a).

(VII-B) ARGUMENT RE. 103(a) REJECTION

REJECTION OF INDEPENDENT CLAIM 1 UNDER 35 U.S.C. § 103 IS IN ERROR

The rejection of claim 1 under 35 U.S.C. § 103(a) as being unpatentable over US patent 4,469,110 to SLAMA in view of U.S. Patent No. 6,156,051 to SCHRAGA is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

The Examiner asserts that the combination of teachings of these documents discloses or suggests the features of claim 1. Appellant respectfully disagrees.

Appellant initially notes that, in rejecting independent claim 1, the Examiner makes numerous assertions based on SLAMA that are improper. For example, on page 4 of the Final Office Action, the Examiner identifies member 5a of SLAMA as the recited trigger and the recited back cap. The Examiner also argues that SLAMA teaches the recited second stop surface as a surface of the front cover 10.

The former assertion is improper because the Examiner has identified a single feature, i.e., the button 5a of SLAMA, as two different recited features, i.e., the recited trigger and the recited back cap. Nor does Appellant understand the clarification provided by the Examiner in the Advisory

Action of November 13, 2009. Member 5 in SLAMA is not the body. The body of SLAMA is member 2. Thus, the statement in the Advisory Action explaining that the "back cap is the closed end of body 5" is hardly clarifying.

Moreover, even if the former assertion were proper (which Appellant disputes), the latter assertion is improper because it is contrary to the express teachings of SLAMA. Contrary to the Examiner's assertions, SLAMA does not provide for contact between a surface of the front cap 10 and the lancet holding member 3. Instead, SLAMA specifically provides for contact between the shaft 5 and the stop surface 7 (see Fig. 3 and col. 3, lines 13-22, 33-38 and 65-68).

Indeed, if SLAMA provided for contact between a surface of the front cap 10 and the lancet holding member 3, SLAMA would no longer have the ability to provide depth adjustment. However, SLAMA specifically provides for depth adjustment using the front cap 10 (see col. 3, lines 54-56).

When one properly interprets the recited first stop surface as being on the shaft 5 of SLAMA and notes that SLAMA specifically describes stop surface 7 as the "second stop" (see col. 2, lines 66-68) and further notes that Fig. 1 of SLAMA shows the stop surface of member 5 as being closer to a rear end of the holding member 3 than to a front end, SLAMA cannot be read to teach or suggest the following:

the front end of the holding member than to the rear end of the holding member, a second stop surface non-movably coupled to the body, and the second stop surface extending inwardly from the body and being arranged closer to a front end of the body than to a rear end of the body and between the first stop surface and the skin engaging end. The shaft 5 is not closer to the front end of the

holding member 3 than to the rear end of the holding member 3. Furthermore, the second stop surface 7 is arranged on a wall of the body 2 in SLAMA (i.e., in slot 2a of body 2) and does not extend inwardly from the body. Indeed, if it did, it would likely obstruct the movement of the holding member 3 whose diameter is shown to almost exactly mach an inside diameter of the body 2 (see Figs. 1, 3 and 4).

SCHRAGA does not cure the deficiencies of SLAMA. First, it is submitted that the Examiner has not set forth a proper obviousness basis. The Examiner, for example, references different embodiments of SCHRAGA (e.g., Figs. 3A-B and Fig. 16) Such embodiments are alternative embodiments which are completely different. In Fig. 3A-B, the depth adjustment is provided at the front end of the holding member via devices 72 and 74 and contact is utilized between the surface of member 32 and pin 28' (see Fig. 7), i.e., the depth adjustment and limiting contact features are arranged on opposite ends of the holding member. In Fig. 16, the depth adjustment is provided at the rear end of the holding member via devices 170 and 172 along with limiting contact between devices 176 and 174. Any obviousness argument based on completely different embodiments must set forth an obviousness basis for combining such different embodiments. This appears absent from the instant Office Action.

It is also submitted that to the extent that the Examiner relies upon Fig. 16 of SCHRAGA as curing the deficiencies of SLAMA, it is submitted that SCHRAGA does not, in point of fact, cure the above-noted deficiencies of SLAMA at least because it also fails to teach of suggest the following claim features:

the front end of the holding member than to the rear end of the holding member, a second stop surface non-movably coupled to the body, and the second stop surface extending inwardly from the body and being arranged closer to a front end of the body than to a rear end of the body and between the first stop surface and the skin engaging end. The first stop surface 176 of SCHRAGA is not closer to the front end of the holding member 30 than to the rear end of the holding member 30. Furthermore, the second stop surface 174 is not arranged closer to a front end of the body than to a rear end of the body and between the first stop surface and the skin engaging end.

Thus, Appellant submits that the above-noted documents fail to disclose or suggest the features recited in at least independent claim 1. Because no proper combination of the above-noted documents discloses or suggests at least the above-noted features of the instant invention, Appellant submits that no proper modification of these documents can render unpatentable the combination of features recited in at least independent claim 1.

Furthermore, Appellant submits that there is no motivation or rationale disclosed or suggested in the art to modify any of the applied documents in the manner asserted by the Examiner. Nor does the Examiner's opinion provide a proper basis for these features or for the motivation to modify these documents, in the manner suggested by the Examiner. Therefore, Appellant submits that the invention as recited in at least independent claim 1 is not rendered obvious by any reasonable inspection of these documents.

Additionally, Appellant submits that the above-noted dependent claims are allowable at least for the reason that these claims depend from an allowable base claim and because these claims recite additional features that further define the present invention.

Appellant requests withdraw and/or reversal of the rejection of the above-noted claim under 35 U.S.C. § 103(a).

REJECTION OF INDEPENDENT CLAIM 43 UNDER 35 U.S.C. § 103 IS IN ERROR

The rejection of claim 43 under 35 U.S.C. § 103(a) as being unpatentable over US patent 4,469,110 to SLAMA in view of U.S. Patent No. 6,156,051 to SCHRAGA is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

The Examiner asserts that the combination of teachings of these documents discloses or suggests the features of claim 43. Appellant respectfully disagrees.

Appellant again initially notes that, in rejecting independent claim 43, the Examiner makes numerous assertions based on SLAMA that are improper. For example, on page 4 of the Final Office Action, the Examiner identifies member 5a of SLAMA as the recited trigger and the recited back cap. The Examiner also argues that SLAMA teaches the recited second stop surface as a surface of the front cover 10.

The former assertion is improper because the Examiner has identified a single feature, i.e., the button 5a of SLAMA, as two different recited features, i.e., the recited trigger and the recited back cap. Nor does Appellant understand the clarification provided by the Examiner in the Advisory Action of November 13, 2009. Member 5 in SLAMA is not the body. The body of SLAMA is

member 2. Thus, the statement in the Advisory Action explaining that the "back cap is the closed end of body 5" is hardly clarifying.

Moreover, even if the former assertion were proper (which Appellant disputes), the latter assertion is improper because it is contrary to the express teachings of SLAMA. Contrary to the Examiner's assertions, SLAMA does not provide for contact between a surface of the front cap 10 and the lancet holding member 3. Instead, SLAMA specifically provides for contact between the shaft 5 and the stop surface 7 (see Fig. 3 and col. 3, lines 13-22, 33-38 and 65-68).

Indeed, if SLAMA provided for contact between a surface of the front cap 10 and the lancet holding member 3, SLAMA would no longer have the ability to provide depth adjustment. However, SLAMA specifically provides for depth adjustment using the front cap 10 (see col. 3, lines 54-56).

When one properly interprets the recited first stop surface as being on the shaft 5 of SLAMA and notes that SLAMA specifically describes stop surface 7 as the "second stop" (see col. 2, lines 66-68) and further notes that Fig. 1 of SLAMA shows the stop surface of member 5 as being closer to a rear end of the holding member 3 than to a front end, SLAMA cannot be read to teach or suggest the following:

a first stop surface arranged <u>on a front portion of the holding member</u> and being disposed inside the body and a second stop surface axially retained to a front portion of the body and <u>being disposed inside the body</u>. The shaft 5 of SLAMA is closer to a rear end of the holding member 3 in Figs. 1 and 3 and, at best, in the middle of the holding member 3 in Fig. 4. Thus, the shaft 5 cannot be said to be a first stop surface arranged <u>on a front portion of the holding member</u>. Furthermore, the second stop surface 7 is arranged on a wall of the body 2 in SLAMA (i.e., in slot 2a

of body 2) and is not <u>inside the body</u>. Indeed, if it were inside body 2, it would likely obstruct the movement of the holding member 3 whose diameter is shown to almost exactly mach an inside diameter of the body 2 (see Figs. 1, 3 and 4).

SCHRAGA does not cure the deficiencies of SLAMA. First, it is submitted that the Examiner has not set forth a proper obviousness basis. The Examiner, for example, references different embodiments of SCHRAGA (e.g., Figs. 3A-B and Fig. 16) Such embodiments are completely different. In Fig. 3A-B, the depth adjustment is provided at the front end of the holding member via devices 72 and 74 and contact is utilized between the surface of member 32 and pin 28' (see Fig. 7), i.e., the depth adjustment and limiting contact features are arranged on opposite ends of the holding member. In Fig. 16, the depth adjustment is provided at the rear end of the holding member via devices 170 and 172 along with limiting contact between devices 176 and 174. Any obviousness argument based on completely different embodiments must set forth an obviousness basis for combining such different embodiments. This appears absent from the instant Office Action.

It is also submitted that to the extent that the Examiner relies upon Fig. 16 of SCHRAGA as curing the deficiencies of SLAMA, it is submitted that SCHRAGA does not, in point of fact, cure the above-noted deficiencies of SLAMA at least because it also fails to teach of suggest the following claim features:

a first stop surface arranged on a front portion of the holding member and being disposed inside the body and a second stop surface axially retained to a front portion of the body and being disposed inside the body. Again, the first stop surface 176 of SCHRAGA is not closer to the

front end of the holding member 30 than to the rear end of the holding member 30. Furthermore, the second stop surface 174 is not axially retained to a front portion of the body.

Thus, Appellant submits that the above-noted documents fail to disclose or suggest the features recited in at least independent claim 43. Because no proper combination of the above-noted documents discloses or suggests at least the above-noted features of the instant invention, Appellant submits that no proper modification of these documents can render unpatentable the combination of features recited in at least independent claim 43.

Furthermore, Appellant submits that there is no motivation or rationale disclosed or suggested in the art to modify any of the applied documents in the manner asserted by the Examiner. Nor does the Examiner's opinion provide a proper basis for these features or for the motivation to modify these documents, in the manner suggested by the Examiner. Therefore, Appellant submits that the invention as recited in at least independent claim 43 is not rendered obvious by any reasonable inspection of these documents.

Additionally, Appellant submits that the above-noted dependent claims are allowable at least for the reason that these claims depend from an allowable base claim and because these claims recite additional features that further define the present invention.

Appellant requests withdraw and/or reversal of the rejection of the above-noted claim under 35 U.S.C. § 103(a).

REJECTION OF INDEPENDENT CLAIM 44 UNDER 35 U.S.C. § 103 IS IN ERROR

The rejection of claim 44 under 35 U.S.C. § 103(a) as being unpatentable over US patent 4,469,110 to SLAMA in view of U.S. Patent No. 6,156,051 to SCHRAGA is in error, the decision of

the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

The Examiner asserts that the combination of teachings of these documents discloses or suggests the features of claim 44. Appellant respectfully disagrees.

Appellant again initially notes that, in rejecting independent claim 44, the Examiner makes numerous assertions based on SLAMA that are improper. For example, on page 4 of the Final Office Action, the Examiner identifies member 5a of SLAMA as the recited trigger and the recited back cap. The Examiner also argues that SLAMA teaches the recited second stop surface as a surface of the front cover 10.

The former assertion is improper because the Examiner has identified a single feature, i.e., the button 5a of SLAMA, as two different recited features, i.e., the recited trigger and the recited back cap. Nor does Appellant understand the clarification provided by the Examiner in the Advisory Action of November 13, 2009. Member 5 in SLAMA is not the body. The body of SLAMA is member 2. Thus, the statement in the Advisory Action explaining that the "back cap is the closed end of body 5" is hardly clarifying. Additionally, even assuming that the Examiner intended to clarify that it is the closed end of body 2 in SLAMA that constitutes the recited back cap, such an assertion would fail to satisfy the claim language which recites that the back cap is configured to move.

Moreover, even if the former assertion were proper (which Appellant disputes), the latter assertion is improper because it is contrary to the express teachings of SLAMA. Contrary to the Examiner's assertions, SLAMA does not provide for contact between a surface of the front cap 10

and the lancet holding member 3. Instead, SLAMA specifically provides for contact between the shaft 5 and the stop surface 7 (see Fig. 3 and col. 3, lines 13-22, 33-38 and 65-68).

Indeed, if SLAMA provided for contact between a surface of the front cap 10 and the lancet holding member 3, SLAMA would no longer have the ability to provide depth adjustment. However, SLAMA specifically provides for depth adjustment using the front cap 10 (see col. 3, lines 54-56).

When one properly interprets the recited first stop surface as being on the shaft 5 of SLAMA and notes that SLAMA specifically describes stop surface 7 as the "second stop" (see col. 2, lines 66-68) and further notes that Fig. 1 of SLAMA shows the stop surface of member 5 as being closer to a rear end of the holding member 3 than to a front end, SLAMA cannot be read to teach or suggest the following:

a first stop surface arranged on a front portion of the holding member and being disposed inside the body and a second stop surface axially retained to a front portion of the body and being disposed inside the body. The shaft 5 of SLAMA is closer to a rear end of the holding member 3 in Figs. 1 and 3 and, at best, in the middle of the holding member 3 in Fig. 4. Thus, the shaft 5 cannot be said to be a first stop surface arranged on a front portion of the holding member. Furthermore, the second stop surface 7 is arranged on a wall of the body 2 in SLAMA (i.e., in slot 2a of body 2) and is not inside the body. Indeed, if it were inside body 2, it would likely obstruct the movement of the holding member 3 whose diameter is shown to almost exactly mach an inside diameter of the body 2 (see Figs. 1, 3 and 4).

SCHRAGA does not cure the deficiencies of SLAMA. First, it is submitted that the Examiner has not set forth a proper obviousness basis. The Examiner, for example, references

different embodiments of SCHRAGA (e.g., Figs. 3A-B and Fig. 16) Such embodiments are completely different. In Fig. 3A-B, the depth adjustment is provided at the front end of the holding member via devices 72 and 74 and contact is utilized between the surface of member 32 and pin 28' (see Fig. 7), i.e., the depth adjustment and limiting contact features are arranged on opposite ends of the holding member. In Fig. 16, the depth adjustment is provided at the rear end of the holding member via devices 170 and 172 along with limiting contact between devices 176 and 174. Any obviousness argument based on completely different embodiments must set forth an obviousness basis for combining such different embodiments. This appears absent from the instant Office Action.

It is also submitted that to the extent that the Examiner relies upon Fig. 16 of SCHRAGA as curing the deficiencies of SLAMA, it is submitted that SCHRAGA does not, in point of fact, cure the above-noted deficiencies of SLAMA at least because it also fails to teach of suggest the following claim features:

a first stop surface arranged on a front portion of the holding member and being disposed inside the body and a second stop surface axially retained to a front portion of the body and being disposed inside the body. Again, the first stop surface 176 of SCHRAGA is not closer to the front end of the holding member 30 than to the rear end of the holding member 30. Furthermore, the second stop surface 174 is not axially retained to a front portion of the body.

Thus, Appellant submits that the above-noted documents fail to disclose or suggest the features recited in at least independent claim 44. Because no proper combination of the above-noted documents discloses or suggests at least the above-noted features of the instant invention, Appellant

submits that no proper modification of these documents can render unpatentable the combination of features recited in at least independent claim 44.

Furthermore, Appellant submits that there is no motivation or rationale disclosed or suggested in the art to modify any of the applied documents in the manner asserted by the Examiner. Nor does the Examiner's opinion provide a proper basis for these features or for the motivation to modify these documents, in the manner suggested by the Examiner. Therefore, Appellant submits that the invention as recited in at least independent claim 44 is not rendered obvious by any reasonable inspection of these documents.

Additionally, Appellant submits that the above-noted dependent claims are allowable at least for the reason that these claims depend from an allowable base claim and because these claims recite additional features that further define the present invention.

Appellant requests withdraw and/or reversal of the rejection of the above-noted claim under 35 U.S.C. § 103(a).

REJECTION OF INDEPENDENT CLAIM 45 UNDER 35 U.S.C. § 103 IS IN ERROR

The rejection of claim 45 under 35 U.S.C. § 103(a) as being unpatentable over US patent 4,469,110 to SLAMA in view of U.S. Patent No. 6,156,051 to SCHRAGA is in error, the decision of the Examiner to reject this claim should be reversed, and the application should be remanded to the Examiner.

The Examiner asserts that the combination of teachings of these documents discloses or suggests the features of claim 45. Appellant respectfully disagrees.

Appellant again initially notes that, in rejecting independent claim 45, the Examiner makes numerous assertions based on SLAMA that are improper. For example, on page 4 of the Final Office Action, the Examiner identifies member 5a of SLAMA as the recited trigger and the recited back cap. The Examiner also argues that SLAMA teaches the recited second stop surface as a surface of the front cover 10.

The former assertion is improper because the Examiner has identified a single feature, i.e., the button 5a of SLAMA, as two different recited features, i.e., the recited trigger and the recited back cap. Nor does Appellant understand the clarification provided by the Examiner in the Advisory Action of November 13, 2009. Member 5 in SLAMA is not the body. The body of SLAMA is member 2. Thus, the statement in the Advisory Action explaining that the "back cap is the closed end of body 5" is hardly clarifying.

Moreover, even if the former assertion were proper (which Appellant disputes), the latter assertion is improper because it is contrary to the express teachings of SLAMA. Contrary to the Examiner's assertions, SLAMA does not provide for contact between a surface of the front cap 10 and the lancet holding member 3. Instead, SLAMA specifically provides for contact between the shaft 5 and the stop surface 7 (see Fig. 3 and col. 3, lines 13-22, 33-38 and 65-68).

Indeed, if SLAMA provided for contact between a surface of the front cap 10 and the lancet holding member 3, SLAMA would no longer have the ability to provide depth adjustment. However, SLAMA specifically provides for depth adjustment using the front cap 10 (see col. 3, lines 54-56).

When one properly interprets the recited first stop surface as being on the shaft 5 of SLAMA and notes that SLAMA specifically describes stop surface 7 as the "second stop" (see col. 2, lines 66-

68) and further notes that Fig. 1 of SLAMA shows the stop surface of member 5 as being closer to a rear end of the holding member 3 than to a front end, SLAMA cannot be read to teach or suggest the following:

a first stop surface arranged on the holding member and being disposed inside the body at a location that is closer to a front end of the body than to a rear end of the body when the holding member is in the intermediate position and a second stop surface arranged inside the body and located closer to the front end of the body than to the rear end of the body. As explained above, the first stop surface is arranged on the shaft 5 of SLAMA and not on the holding member 3. Furthermore, the stop surface of the shaft 5 is not arranged inside the body 2. Instead, it i9s arranged on the portion of the shaft 5 that moves in slot 2a of the body 2. Moreover, the second stop surface 7 is arranged on a wall of the body 2 in SLAMA and is not inside the body. Indeed, if it were inside body 2, it would likely obstruct the movement of the holding member 3 whose diameter is shown to almost exactly mach an inside diameter of the body 2 (see Figs. 1, 3 and 4).

SCHRAGA does not cure the deficiencies of SLAMA. First, it is submitted that the Examiner has not set forth a proper obviousness basis. The Examiner, for example, references different embodiments of SCHRAGA (e.g., Figs. 3A-B and Fig. 16) Such embodiments are completely different. In Fig. 3A-B, the depth adjustment is provided at the front end of the holding member via devices 72 and 74 and contact is utilized between the surface of member 32 and pin 28' (see Fig. 7), i.e., the depth adjustment and limiting contact features are arranged on opposite ends of the holding member. In Fig. 16, the depth adjustment is provided at the rear end of the holding member via devices 170 and 172 along with limiting contact between devices 176 and 174. Any

obviousness argument based on completely different embodiments must set forth an obviousness basis for combining such different embodiments. This appears absent from the instant Office Action.

It is also submitted that to the extent that the Examiner relies upon Fig. 16 of SCHRAGA as curing the deficiencies of SLAMA, it is submitted that SCHRAGA does not, in point of fact, cure the above-noted deficiencies of SLAMA at least because it also fails to teach of suggest the following claim features:

a first stop surface arranged on the holding member and being disposed inside the body at a location that is closer to a front end of the body than to a rear end of the body when the holding member is in the intermediate position and a second stop surface arranged inside the body and located closer to the front end of the body than to the rear end of the body. The first stop surface 176 of SCHRAGA is not disposed inside the body at a location that is closer to a front end of the body than to a rear end of the body when the holding member 30 is in the intermediate position. Furthermore, the second stop surface 174 is not arranged closer to the front end of the body than to the rear end of the body.

Thus, Appellant submits that the above-noted documents fail to disclose or suggest the features recited in at least independent claim 45. Because no proper combination of the above-noted documents discloses or suggests at least the above-noted features of the instant invention, Appellant submits that no proper modification of these documents can render unpatentable the combination of features recited in at least independent claim 45.

Furthermore, Appellant submits that there is no motivation or rationale disclosed or {P23568 00802404.DOC}

suggested in the art to modify any of the applied documents in the manner asserted by the Examiner. Nor does the Examiner's opinion provide a proper basis for these features or for the motivation to modify these documents, in the manner suggested by the Examiner. Therefore, Appellant submits that the invention as recited in at least independent claim 45 is not rendered obvious by any reasonable inspection of these documents.

Additionally, Appellant submits that the above-noted dependent claims are allowable at least for the reason that these claims depend from an allowable base claim and because these claims recite additional features that further define the present invention.

Appellant requests withdraw and/or reversal of the rejection of the above-noted claim under 35 U.S.C. § 103(a).

REJECTION OF DEPENDENT CLAIMS 2, 3, 8-14, 17-33, 35-42 AND 46-48 UNDER 35 U.S.C. § 103 IS IN ERROR

Claims 2, 3, 8-14, 17-33, 35-42 and 46-48 respectfully depend from independent claims 1 and 43-45, and are believed to be allowable based at least on their dependence to these independent claims.

CONCLUSION

Each of claims 1-3, 8-14, 17-33 and 35-48 are patentable under 35 U.S.C. §§ 112, 102(b) and 103(a). Specifically, the applied art of record, even if properly combined, fails to disclose or suggest the unique combination of features recited in Appellant's claims 1-3, 8-14, 17-33 and 35-48. Accordingly, Appellant respectfully requests that the Board reverse the decision of the Examiner to reject claims 1-3, 8-14, 17-33 and 35-48 under 35 U.S.C. §§ 102(b) and 103(a), and remand the application to the Examiner for withdrawal of the above-noted rejections.

Respectfully submitted, S. SCHRAGA

March 12, 2010 GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clarke Place Reston, VA 20191 703-716-1191 Neil F. Greenblum Reg. No. 28,394

Stephen M. Roylance Reg. No. 31,296

Attachments: Claims Appendix, Evidence Appendix, and Related Proceedings Appendix

VIII CLAIMS ON APPEAL

- 1. A lancet device, comprising:
- a body;
- a trigger movably mounted to the body;
- a front cover removably mounted to the body and comprising a skin engaging end that includes a lancet opening through which a lancet needle may extend;
- a holding member movably mounted within the body and comprising a front end and a rear end;
- a main spring disposed inside the body between the front and rear ends of the holding member;

the front end being configured to receive a lancet;

- a first stop surface that moves with the holding member and being arranged closer to the front end of the holding member than to the rear end of the holding member;
 - a second stop surface non-movably coupled to the body; and

the second stop surface extending inwardly from the body and being arranged closer to a front end of the body than to a rear end of the body and between the first stop surface and the skin engaging end,

wherein at least partial rotation of the front cover causes the skin engaging end to move axially relative to the second stop surface, and

wherein contact between the first and second stop surfaces defines a puncturing position of the lancet needle.

- 2. The lancet device of claim 1, further comprising a back cap configured to move between a retracted position and an original position.
- 3. The lancet device of claim 2, wherein the back cap is configured to move the holding member to a retracted position.

- 8. The lancet device of claim 2, further comprising another spring for biasing the back cap towards an original position.
- 9. The lancet device of claim 1, wherein the main spring biases the holding member towards an extended position, and further comprising another spring for biasing the holding member in an opposite direction.
- 10. The lancet device of claim 9, wherein said main spring and said other spring are arranged to surround portions of the holding member.
- 11. The lancet device of claim 9, wherein the main spring is coupled one side of the holding member and to a surface of the body.
- 12. The lancet device of claim 11, wherein the holding member comprises cylindrical surfaces and a polygonal cross-sectional shape.
- 13. The lancet device of claim 11, further comprising a locking member mounted to the rear end of the holding member.
- 14. The lancet device of claim 13, wherein the main spring surrounds a portion of the holding member and wherein the other spring is disposed between a surface of a back cap and the locking member.
- 17. The lancet device of claim 1, further comprising a mechanism for at least temporarily maintaining a depth setting position of the front cover.
- 18. The lancet device of claim 1, wherein the holding member comprises an integrally formed deflecting member that engages a surface of the body.

- 19. The lancet device of claim 1, wherein the front end comprises an opening that is configured to removably receive the lancet.
- 20. The lancet device of claim 1, further comprising a deflecting member configured to be deflected by the trigger.
- 21. The lancet device of claim 20, wherein the deflecting member is coupled to the holding member.
- 22. The lancet device of claim 20, wherein the deflecting member comprises an engaging surface that contacts a surface of the body.
- 23. The lancet device of claim 22, wherein the deflecting member is integrally formed with the holding member.
- 24. The lancet device of claim 1, further comprising indicia arranged on at least one of the front cover and the body.
- 25. The lancet device of claim 24, wherein the indicia is arranged on an outer circumferential surface of the body.
- 26. The lancet device of claim 24, wherein the indicia is arranged on an outer circumferential surface of the front cover.
- 27. The lancet device of claim 1, wherein the holding member comprises a front portion that includes the front end and a rear portion that includes the rear end, wherein the front and rear portions are connected together.

- 28. The lancet device of claim 27, wherein the rear portion comprises a locking end which receives a locking member.
- 29. The lancet device of claim 28, wherein the front portion comprises a deflecting member configured to be deflected by the trigger.
- 30. The lancet device of claim 1, wherein the front cover rotates about an axis that runs through the lancet opening and the holding member.
- 31. The lancet device of claim 1, wherein the main spring is disposed between the trigger and a back cap.
 - 32. The lancet device of claim 1, wherein the body comprises a two-piece body.
- 33. The lancet device of claim 32, further comprising another spring axially retained between walls of the two-piece body.
- 35. The lancet device of claim 33, further comprising a back cap movably mounted to the two-piece body.
 - 36. The lancet device of claim 1, wherein the body comprises an ergonomic shape.
 - 37. The lancet device of claim 1, wherein the body comprises cylindrical surfaces.
 - 38. The lancet device of claim 1, wherein the body comprises a plastic material.
 - 39. The lancet device of claim 1, wherein the front cover comprises gripping protrusions.

- 40. The lancet device of claim 1, further comprising threads connecting the front cover to the body.
- 41. A method of puncturing a surface of skin using the lancet device of claim 1, the method comprising:

adjusting a set depth of penetration of the needle by rotating the front cover to a desired set position;

disposing the skin engaging end of the lancet device against a user's skin; and triggering the trigger to cause the lancet needle to penetrate the user's skin, wherein the puncture allows a blood sample to be taken.

- 42. A method of using the lancet device of claim 1, the method comprising: rotating the front cover to a desired set position; moving the holding member to a retracted position; maintaining the holding member in the retracted position until the trigger is triggered; disposing the skin engaging end of the lancet device against a user's skin; and triggering the trigger to cause movement of the holding member.
- 43. A lancet device, comprising:
- a body;
- a front cover comprising a skin engaging end that includes a lancet opening through which a lancet needle may extend;
- a holding member movably mounted within the body, the holding member comprising a front end and a rear end;

the front end being configured to receive a lancet;

a main spring disposed inside the body and between the front and rear ends of the holding member;

a first stop surface arranged on a front portion of the holding member and being disposed inside the body; and

a second stop surface axially retained to a front portion of the body and being disposed inside the body,

wherein at least partial rotation of the front cover causes the skin engaging end to move axially relative to the second stop surface, and

wherein contact between the first and second stop surfaces defines a puncturing position of the lancet needle.

- 44. A lancet device, comprising:
- a body;
- a trigger;
- a front cover comprising a skin engaging end that includes a lancet opening through which a lancet needle may extend;
- a holding member movably mounted within the body, the holding member comprising a front end and a rear end;
 - the front end being configured to receive a lancet;
- a first spring disposed inside the body between the front end of the holding member and a surface of the body;
- a back cap configured to move the holding member to a retracted position and having a portion which extends within a rear portion of the body;
- a second spring disposed between the rear end of the holding member and a surface of the back cap;
- a first stop surface coupled to a front portion of the holding member and being disposed inside the body; and
- a second stop surface axially retained to a front portion of the body and being disposed inside the body,

wherein at least partial rotation of the front cover causes the skin engaging end to move axially relative to the second stop surface, and

wherein contact between the first and second stop surfaces defines a puncturing position of the lancet needle.

- 45. A lancet device, comprising:
- a body;
- a trigger mounted to the body;
- a removable front cover comprising a skin engaging end that includes a lancet opening through which a lancet needle may extend;
- a holding member movably mounted within the body and comprising a rear end and a front end configured to receive a lancet;
- a wall arranged within the housing and comprising an opening which allows a portion of the holding member to pass therethrough;
- a first spring structured and arranged to move the holding member to an extended position and comprising one end which contacts a portion of the holding member;
- a second spring structured and arranged to move the holding member from the extended position to an intermediate position;
- a first stop surface arranged on the holding member and being disposed inside the body at a location that is closer to a front end of the body than to a rear end of the body when the holding member is in the intermediate position; and
- a second stop surface arranged inside the body and located closer to the front end of the body than to the rear end of the body,
- wherein, when the holding member is positioned in a trigger-set position, the front end is arranged on a front side of the wall and the rear end is arranged on back side of the wall, and wherein contact between the first and second stop surfaces defines the extended position.

- 46. The lancet device of claim 45, wherein a triggering of the lancet device is cause by movement of the trigger against the biasing force of the trigger spring and by deflection of a deflectable portion of the holding member.
- 47. The lancet device of claim 45, wherein a triggering of the lancet device is cause by the following:

movement of the trigger; and

deflection of a deflectable portion of the holding member from a position wherein a surface of the deflectable portion contacts a portion of the body to a position wherein the surface of the deflectable portion does not contact the portion of the body.

48. The lancet device of claim 45, wherein a triggering of the lancet device is cause by the following:

movement of the trigger from the initial position to a position wherein a portion of the trigger contacts a deflectable portion of the holding member; and

deflection of the deflectable portion of the holding member from a position wherein a surface of the deflectable portion contacts a portion of the body to a position wherein the surface of the deflectable portion does not contact the portion of the body.

IX EVIDENCE APPENDIX

This section lists evidence submitted pursuant to 35 C.F.R. §§1.130, 1.131, or 1.132, or any other evidence entered by the Examiner and relied upon by Appellant in this appeal, and provides for each piece of evidence a brief statement setting forth where in the record that evidence was entered by the Examiner. Copies of each piece of evidence are provided as required by 35 C.F.R. §41.37(c)(ix).

		BRIEF STATEMENT SETTING
		FORTH WHERE IN THE RECORD
NO.	EVIDENCE	THE EVIDENCE WAS ENTERED BY
		THE EXAMINER
1	N/A	N/A

X RELATED PROCEEDINGS APPENDIX

Pursuant to 35 C.F.R. §41.37(c)(x), copies of the following decisions rendered by a court of the Board in any proceeding identified above under 35 C.F.R. §41.37(c)(1)(ii) are enclosed herewith.

NO.	TYPE OF PROCEEDING	REFERENCE NO.	DATE
1	Prior Appeal to the Board	Appeal 2007-1749	3-28-08



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/641,142	08/15/2003	Steven Shraga	P23568	8544
7055 GREENBLUM	7590 04/01/2008 I & BERNSTEIN, P.L.C.	EXAMINER		
1950 ROLANI	O CLARKE PLACE		NGUYEN, ANH TUAN TUONG	
RESTON, VA	20191		ART UNIT	PAPER NUMBER
			3731	
	•			
			NOTIFICATION DATE	DELIVERY MODE
			04/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte STEVEN SHRAGA

Appeal 2007-1749 Application 10/641,142 Technology Center 3700

Decided: March 28, 2008

Before TERRY J. OWENS, JENNIFER D. BAHR, and DAVID B. WALKER, *Administrative Patent Judges*.

WALKER, Administrative Patent Judge.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant seeks our review under 35 U.S.C. § 134 of the Examiner's final rejection of claims 1-3 and 8-44. We have jurisdiction under 35 U.S.C. § 6(b) (2002). We affirm.

Appellant claims a lancet device preferably having an adjusting capability and a method of using a lancet device (Specification 1:[0001]). Claim 1, reproduced below, is representative of the subject matter on appeal.

1. A lancet device, comprising:

a body;

a trigger;

a front cover comprising a skin engaging end that includes a lancet opening through which a lancet needle may extend;

a holding member movably mounted within the body and comprising a front end and a rear end;

a main spring disposed between the front and rear ends of the holding member;

the front end being configured to receive a lancet;

a first stop surface that moves with the holding member;

a second stop surface non-movably coupled to the body; and

the second stop surface extending inwardly from the body and being arranged between the first stop surface and the skin engaging end, wherein at least partial rotation of the front cover causes the skin engaging end to move axially relative to the second stop surface.

THE REJECTIONS

The Examiner relies upon the following as evidence in support of the rejections:

Slama	US 4,469,110	Sep. 4, 1984
Schraga	US 6,156,051	Dec. 5, 2000

The following rejections are before us for review.

- 1. Claims 1-3, 8-23, 27-31, and 36-42 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as unpatentable over Schraga.
- 2. Claims 24-26 and 32-35 are rejected under 35 U.S.C. § 103(a) as unpatentable over Schraga.
- 3. Claims 43 and 44 are rejected under 35 U.S.C. § 103(a) as unpatentable over Slama.

ISSUE

The issue before us is whether Appellant has shown that the Examiner erred in rejecting: 1) claims 1-3, 8-23, 27-31, and 36-42 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as unpatentable over Schraga; 2) claims 24-26 and 32-35 under 35 U.S.C. § 103(a) as unpatentable over

Schraga; and 3) claims 43 and 44 are rejected under 35 U.S.C. § 103(a) as unpatentable over Slama. The dispositive issue is whether the cited prior art teaches a lancet device wherein at least partial rotation of the front cover causes the skin engaging end to move axially relative to the second stop surface.

Rather than repeat the arguments of Appellant and the Examiner, we make reference to the Briefs and the Answer for their respective details. Only those arguments actually made by Appellant have been considered in this decision. Arguments which Appellant could have made but chose not to make in the Briefs have not been considered and are deemed to be waived. *See* 37 C.F.R. § 41.37(c)(1)(vii) (2004).

FINDINGS OF FACT

We find the following enumerated findings to be supported by at least a preponderance of the evidence. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

1. Schraga discloses a lancet device with a trigger similar to those shown in the embodiments of Figures 1-7 for use with the embodiment of Figure 16. Figure 16 shows a body (middle housing 20C), a holding member 30, a main spring 40 disposed between the front and rear ends of the holding member, a first stop surface (flange 176) that moves with the holding member, a second stop surface (guide collar 174) non-movably

- coupled to the body and extending inwardly from the body and being arranged between the first stop surface and the skin engaging end (Schraga, col. 14, ll. 52-59; Fig. 16).
- 2. Schraga also teaches a cap segment 50 will be removably fitted on the housing 20 preferably through corresponding proportioning of an interior dimension of the open first side 51 of the cap segment 50 relative to the open second end 24 of the housing 20, but alternatively engagement ridges or a similar removable fastener system may be included to secure the cap segment 50 on the housing 20. Other removable fastener systems include threads, locking clips, and locking buttons (Schraga, col. 10, ll. 18-26).
- 3. One of skill in the art would have understood that removably fastening cover 50 to part 20A (shown in Figure 16) would cause part 20A to rotate with cover 50 if the cover 50 is rotated, causing parts 20A and 50 in combination to act as a cover as required by claim 1. Because part 20A is threadedly connected to body 20C via threads 170 and 172 (Schraga, Figure 16), one of skill in the art would have recognized that at least partial rotation of the front cover would cause the skin engaging end of cover 50 to move axially relative to the second stop surface.
- 4. Schraga explicitly teaches that although the cap segment is shown in Figure 8 as being triangular, it may be other shapes depending on the shape of the housing (Schraga, col. 10, ll. 3-12).

- 5. Schraga further teaches that indicia can be included on members that change position relative to each other when the penetration depth is adjusted in order to assist in determining the penetration depth of the insert (Schraga, col. 16, ll. 46-59).
- 6. Schraga further teaches a back cap configured to move the holding member to a retracted position and a second spring disposed between the rear end of the holding member and a surface of the back cap (Schraga, col. 14, ll. 52-59; Fig. 16).
- 7. Slama teaches a lancet device with a cover (labeled body 2) with an opening 8 through which the pin 1 is to project. The cover includes a threaded sleeve that permits the pin to advance relative to the body. The point of pin 1 can penetrate more or less deeply into the skin according to the degree of screwing the sleeve 10 into the cover. Each user can set the desired depth of penetration according to his skin and his preference. For facilitating the adjustment, a graduation scale 10a has been provided on the sleeve 10 and a mark 2b on the cover (Slama, col. 3, 11. 50-64).

PRINCIPLES OF LAW

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987).

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1734 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of ordinary skill in the art, and (4) where in evidence, so-called secondary considerations. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). See also KSR, 127 S.Ct. at 1734 ("While the sequence of these questions might be reordered in any particular case, the [Graham] factors continue to define the inquiry that controls.")

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a prima facie case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). *See also In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Only if this initial burden is met does the burden of coming forward with evidence or argument shift to the appellant. *Id.* at 1445. *See also Piasecki*, 745 F.2d at 1472. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *See Oetiker*, 977 F.2d at 1445; *Piasecki*, 745 F.2d at 1472.

ANALYSIS

A. Rejection of claims 1-3, 8-23, 27-31, and 36-42 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as unpatentable over Schraga.

Appellant advances several arguments for why claim 1 is neither anticipated by nor obvious over Schraga; all of which are predicated on the Appellant's interpretation that part 20A of Schraga is the body of the lancet device as defined in claim 1. Appellant provides no support for his insistence that 20A, and not 20C, is the body, except for a conclusory statement that Schraga clearly shows a front cover 50 and a body 20/20A (Reply Br. 2). We disagree.

For example, Appellant argues that the Examiner is incorrect that member 174 is non-movably coupled to the body 20A (Br. 7-8). The Examiner's rejection, however, found that 20C is analogous to the body as required by claim 1 and that member 174 is a second stop surface that is nonmovably coupled to the body 20C (Answer 3). We find the Examiner's reading of Schraga to be reasonable (Findings of Fact 1-3). Because Schraga meets the disputed claim limitation under the Examiner's reasonable interpretation, we find the Appellant's argument not to be persuasive.

Appellant further argues that cover 50 has a triangular cross section and slides onto a triangular portion of the body 20, and thus cannot possibly rotate relative to the body 20A (Br. 8). Appellant's argument is not persuasive because the Examiner's rejection in fact relies on the fact that cover 50 does not rotate

relative to part 20A, but rather in combination forms a cover. The Examiner found that the combination of parts 20A and 50 forms a cover as required by claim 1 and at least partial rotation of the front cover 20A, 50 causes the skin engaging end (at the distal end of 50) to move axially relative to the second stop surface due to the threaded connection at 170, 172 (Answer 4 citing Schraga, col. 14, ll. 21-24). We agree with the Examiner that Schraga teaches all of the limitations of and therefore anticipates claim 1 (Findings of Fact 1-3). Appellant has not shown error in the Examiner's rejection of claim 1. Claims 2-3, 8-16, 18-23, 27-29, 31, 36-38, and 41 were not argued separately, and fall with claim 1. See 37 C.F.R. § 41.37(c)(1)(vii). See also In re Young, 927 F.2d 588, 590 (Fed. Cir. 1991).

With respect to claim 17, Appellant separately argues that Schraga fails to disclose any penetration depth adjustment between the front cover 50 and body 20 (Br. 9). Similar to the arguments advanced against the rejections of claim 1, this argument depends on the Appellant's erroneous interpretation of Schraga. Under the Examiner's interpretation of the parts of Schraga, the threaded connection between parts 20A and 20C provides a mechanism for temporarily maintaining a depth setting position of the cover as required by claim 17 (Finding of Fact 3). Appellant has not shown error in the Examiner's rejection of claim 17.

With respect to claim 30, the Appellant argues that Schraga discloses a triangular front cover 50 that slides onto the body 20 and that does not rotate relative to the body 20 (Br. 10). As discussed in reference to claim 1, Figure 16 of Schraga shows that part 20A (which acts in combination with cover 50 as a cover)

rotates about an axis that runs through the lancet opening and the holding member via threads 170 and 172 (Finding of Fact 3). The Appellant has not shown error in the Examiner's rejection of claim 30.

With respect to claim 39, Appellant relies on the same position that the cover doesn't rotate argued with respect to the above rejections, and thus argues the front cover lacks the gripping projections required by claim 39. The Examiner found that Schraga discloses gripping protrusions at the corners of the triangular shaped front cover 20A, 50. We agree with the Examiner that the corners of a triangular shaped cover can serve as gripping protrusions as required by claim 39. The Appellant has not shown error in the Examiner's rejection of claim 39.

With respect to claim 40, Appellant argues that Schraga does not teach threads connecting the front cover to the body. This argument depends on the Appellant's erroneous interpretation of Schraga asserted with respect to claim 1. Because the cover 20A, 50 is connected to body 20C by threads 170, 172, Appellant has not shown error in the Examiner's rejection of claim 40.

The Appellant similarly argues that the Examiner's rejection of claim 42 is improper because Schraga does not teach rotating the front cover to a desired position. Because the cover 20A, 50 rotates relative to body 20C via threads 170, 172, Appellant has not shown error in the Examiner's rejection of claim 42.

B. Rejection of claims 24-26 and 32-35 under 35 U.S.C. § 103(a) as unpatentable over Schraga.

Appellant argues only claim 26. The Appellant restates the arguments found to be unpersuasive with respect to the above rejections over Schraga. Those arguments are equally unpersuasive as to this rejection. The Appellant further argues that it would not make sense to arrange indicia on an outer circumferential surface of the cover because: 1) the front cover 50 is disclosed as triangular and thus lacks an outer circumferential surface; and 2) the front cover does not participate in penetration depth adjustment. We find this argument unpersuasive because the triangular cover shape is only one of several configurations taught by Schraga (Finding of Fact 4), and the front cover as construed by the Examiner does participate in penetration depth adjustment. Moreover, Schraga further teaches that indicia can be included on members that change position relative to each other when the penetration depth is adjusted in order to assist in determining the penetration depth of the insert (Finding of Fact 5). The Appellant has failed to show error in the Examiner's rejection of claim 26. Claims 24-25 and 32-35 were not argued separately, and fall with claim 26. See 37 C.F.R. § 41.37(c)(1)(vii). See also Young, 927 F.2d at 590 (Fed. Cir. 1991).

C. Rejection of claims 43 and 44 under 35 U.S.C. § 103(a) as unpatentable over Slama.

Appellant argues that no proper combination of the cited references discloses or suggests a main spring disposed between the front and rear ends of the holding member and a second stop surface axially retained to a front portion of the body, as recited in independent claim 43 (Br. 15). We find this argument unpersuasive because these features are taught by Schraga (Finding of Fact 1).

Appellant argues that no proper combination of the cited references discloses or suggests a back cap configured to move the holding member to a retracted position, a second spring disposed between the rear end of the holding member and a surface of the back cap, and a second stop surface axially retained to a front portion of the body, as recited in independent claim 44 (Br. 18). We find this argument unpersuasive because these features are taught by Schraga (Findings of Fact 1 & 6). The Appellant has failed to show error in the Examiner's rejection of claims 43 and 44.

CONCLUSIONS

We conclude that Appellant has not shown that the Examiner erred in rejecting claims 1-3, 8-23, 27-31, and 36-42 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as unpatentable over Schraga. We conclude that Appellant has not shown that the Examiner erred in

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rejecting claims 24-26 and 32-35 under 35 U.S.C. § 103(a) as unpatentable over Schraga. We conclude that Appellant has not shown that the Examiner erred in rejecting claims 43 and 44 under 35 U.S.C. § 103(a) as unpatentable over Slama.

DECISION

The decision of the Examiner to reject claims 1-3 and 8-44 is affirmed. No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). See 37 C.F.R. § 1.136(a)(1)(iv) (2006).

<u>AFFIRMED</u>

ilb

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